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Reclassification of CPR Aids

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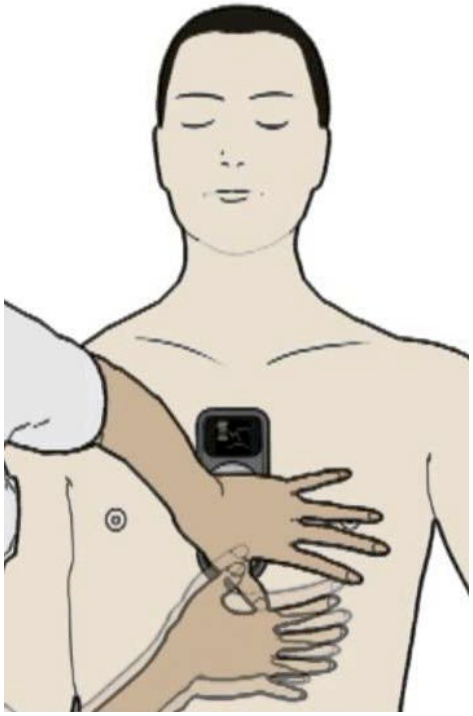
Laerdal CPR Meter



After several years of widespread use and refinement of design, CPR Aid technology is quite mature and its value well proven.

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AHA Consensus Statement

CPR Quality: Improving Cardiac Resuscitation Outcomes Both Inside and Outside the Hospital

A Consensus Statement From the American Heart Association

Endorsed by the American College of Emergency Physicians

Peter A. Meaney, MD, MPH, Chair; Bentley J. Bobrow, MD, FAHA, Co-Chair;
Mary E. Mancini, RN, PhD, NE-BC, FAHA; Jim Christenson, MD; Allan R. de Caen, MD;
Farhan Bhanji, MD, MSc, FAHA; Benjamin S. Abella, MD, MPhil, FAHA;

"Without CPR measurement and subsequent understanding of CPR performance, improvement and optimized performance cannot occur. Providing CPR without monitoring performance can be likened to flying an airplane without an altimeter"

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Laerdal proposes that *all* CPR Aids,

not just those that do not provide feedback,

should be *510(k) exempt*.

CPR Aids: Risks to health

Risks to health identified by FDA:

- Adverse skin reactions due to device material
- Suboptimal CPR due to improper feedback

Suboptimal CPR

- MDR reports for past 12 years: no reports of inaccurate feedback.
- The *theoretical* risk of providing inaccurate feedback should be weighed against the e*stablished fact* of sub-optimal CPR:
  - 60% of compressions performed by professional rescuers do not meet AHA guidelines for compression depth.

CPR Aids provide a tremendous opportunity to improve the quality of CPR.

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Because CPR Aids have a *low risk profile*,

it is *unnecessary* for FDA to allocate resources for premarket review of these devices,

***especially* if CPR Aids are required to provide feedback *in accordance with AHA guidelines*.**

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The presence or absence of software is immaterial to whether 510(k) is needed.

- Software in CPR Aids is a *mature, relatively simple* technology.
- Even non-software devices *could* fail and lead to suboptimal CPR.
- All CPR Aids are simple devices, *whether controlled by software or not*.
- The criteria to justify 510(k) exemption for CPR Aids *without* software apply equally well to those *with* software.

Conclusion

CPR Aids do not need 510(k) review, regardless of:

- ***Whether or not*** **they have software.**
- ***Whether or not*** **they provide real-time feedback.**
- **Whether their users are *highly trained professionals or not*.**